JUN 23 2006

Exhibit #1 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _K060281_____.

Submitter:

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- **Contact Person:**

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- **Date Prepared:**

Jan. 16, 2005

Name of the device:

- **Trade/Proprietary Name:** VS-800 Vital Signs Monitor
- **Common Name:** Vital Signs Monitor
- **Classification**

21 CFR 870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	Class □
21 CFR 870.1130	Non-Invasive blood pressure measurement System	Class □
21 CFR 870.2700	Oximeter, Pulse	Class □
21 CFR 870.2710	Ear Oximeter, Pulse	Class □

Legally Marketed Predicate Device:

K043348 PM-8000 Patient Monitor (by Mindray Co., Ltd.)

Description:

The VS-800 Vital Signs Monitor is battery or line-powered monitor used on human patient. The Vital Signs Monitor acquires the physiological signals non-invasive blood pressure (NIBP) and pulse oxygen saturation of the blood (SpO2). These physiological signals are converted into digital data and processed. The VS-800 Vital Signs Monitor examines the data for alarm conditions and presents them on the front panel. The Vital Signs Monitor also provides user with the convenient operating control and human-machine interface (HMI).

The optional built-in recorder provides hard copies of all digital data and waveforms as well as Tabular and Graphic Trend Information, and storage the previous monitoring data information when power off accidentally.

Statement of intended Use:

This device is used to monitor physiologic parameters, including SpO_2, PR and NIBP, on adult, pediatric, and neonatal patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

This device is not intended for transport or home use.

Comparison of Technological Characteristics:

The VS-800 Vital Signs Monitor is substantially equivalent to systems currently marketed predicate devices. The design, components, storage technology and energy source of the VS-800 Vital Signs Monitor are similar to the predicate device named PM-8000 Patient Monitor (K#043348). Both VS-800 Vital Signs Monitor and PM-8000 Patient Monitor provide a means for interfacing with a patient, collecting parameter specific physiological data, and processing the data for alarm generation and display of numeric values and waveforms on a bedside or central monitoring system. The monitoring parameters of the PM-8000 Patient Monitor cover those of the VS-800 Vital Signs Monitor. And the parameters' specification of the VS-800 Vital Signs Monitor, including SpO2, PR and NIBP, is similar to the predicate PM-8000 Patient Monitor.

The notable difference between the technical specifications of the VS-800 Vital Signs Monitor and PM-8000 Patient Monitor is shown as following:

While the monitoring parameters of the PM-8000 Patient Monitor cover those of the VS-800 Vital Signs Monitor, but the parameters' specification of the VS-800 Vital Signs Monitor, including SpO2, PR and NIBP, is similar to the predicate PM-8000 Patient Monitor, and all these parameters of the pending device and the predicate device comply with some

ANSI/AAMI standards, IEC standards, EN standards and ISO standards.

These technological differences do not affect the safety or efficacy of the device. Any safety issues that may be raised by a software controlled medical device are the same issues already addressed by the predicate device and are addressed in the systems hazard analysis and in the system validation.

Testing:

Laboratory testing was conducted to validate and verify that the VS-800 Vital Signs Monitor met all design specifications and was substantially equivalent to the predicate devices. This testing consisted of all environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. Finally, a hazard analysis of the system and its software was performed and testing was conducted to validate the systems overall operation. Some safety testing has been performed by third party agencies to ensure the device complies with applicable industry and safety standards. The VS-800 Vital Signs Monitor has also been tested to assure compliance with the requirements of various published standards, including EN865, IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, IEC60601-2-30, and ISO14971.

Testing of the non-invasive blood pressure portion of the system was conducted according to the requirements outlined in the ANSI/AAMI Standards SP10 "Electronic automated sphygmomanometers."

Although the device is neither life supporting nor life sustaining, diagnostic information derived from the use of the device and alarms generated by the device may be critical to the proper management of the patient. So, the areas of risk for this device are the same as other devices in this class, and the following:

- Electrical shock

  Excessive electrical chassis leakage current can disturb the normal electrophysiology of the heart.
- Misdiagnosis
  - Inadequate design of the signal processing and measurement circuitry or program can lead generation of inaccurate diagnostic data.. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
  - Inadequate design of the device's software, used to make various measurements, can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
  - Inadequate design of the systems ability to alert the users through audible and

visual indicators, can lead to user mistrust and/or inadequate response to the patient's condition. If an inadequate response to the patient's condition should occur the patient may unnecessarily be placed at risk.

Conclusion:

The conclusions drawn from clinical and laboratory testing of the VS-800 Vital Signs Monitor demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the PM-8000 Patient Monitor numbered K#043348(by Mindray Co., Ltd).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2006

Shenzhen Mindray Bio-Medical Electronics Co. Ltd.
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K060281
Trade Name: VS-800 Vital Signs Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with Arrhythmia Detection or Alarms)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: June 16, 2006
Received: June 19, 2006

Dear Ms. Goldstein-Falk:

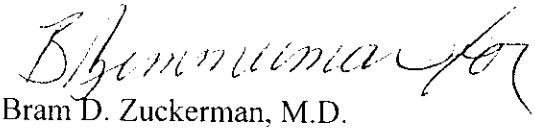
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-_0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Heath

Enclosure

510(k) Number (if known): K060281

Device Name: VS-800 Vital Signs Monitor

Indications For Use:

The VS-800 Vital Signs Monitor is used to monitor physiological parameters, including Sp02, PR and NIBP on adults, pediatric and neonatal patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

The device is not intended for transport or home use.

Prescription Use X **(Per 21 CFR 801 Subpart D)** OR **Over-The Counter Use** _____ **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060281